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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,393	02/17/2005	Walter Messier	GENO200.1-7/PCT-US	6312
25871 7590 12/04/2007 SWANSON & BRATSCUN, L.L.C. 8210 SOUTHPARK TERRACE LITTLETON, CO 80120			EXAMINER MARTINELL, JAMES	
			ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
			12/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/522,393

**Applicant(s)**

MESSIER, WALTER

**Examiner**

James Martinell

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, and 5-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, and 5-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "commercially or aesthetically relevant trait" (claims 1, 3, and 12) vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 2, item (a)). Applicant's arguments (response filed September 24, 2007, page 7) are not convincing. First, applicant does not address the rejection based on the use of the term, "aesthetically." Second, applicant merely asserts that one of "skill in the art can readily identify those traits that are commercially relevant" without providing any evidence to support the assertion. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action.
- (b) The recitation of "relevant trait" (claims 1, 3, and 12) is vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 2, item (b)). Applicant's arguments (response filed September 24, 2007, paragraph bridging pages 7-8) are not convincing. Applicant complains that the term, "relevant trait", cannot be separated from "commercially or aesthetically", but offer no clarifying explanation or argument or evidence. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of

the specification are not numbered. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action.

- (c) The recitation of "evolutionary bottleneck" (claims 1, 3, and 12) is vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 2, item (c)). Applicant's arguments (response filed September 24, 2007, page 8) are not convincing. Applicant asserts that the evolutionary bottleneck analysis is done by "standard methods in the art", yet applicant points to no particular standard method, making only general statements standard analytical methods exist. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action.
- (d) The recitation of "detecting a region of polynucleotide sequence wherein the evolutionary bottleneck analysis indicates an evolutionary bottleneck" (claims 1 and 3) is vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 2, item (d)). Applicant's arguments (response filed September 24, 2007, paragraph bridging pages 8-9) are not convincing. Applicant asserts that the methods require finding a positive signal of a nucleotide region having been through an evolutionary bottleneck as being based on detection of lower nucleotide diversity in the region that has been "evolutionarily bottlenecked". How this can be done with a sample size as small as two individuals (*e.g.*, claims 1 and 3) is unexplained. Two individuals at any one nucleotide locus can show a maximum of 4 different nucleotides (one on each of the homologous

chromosomes). With this result, and the instant disclosure, one of skill in the art cannot know, with clarity, whether an evolutionary bottleneck is to be inferred or not. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action.

(e) Claims 6 and 15 are vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 3, item (f)). The instant application does not define  $n$ . Applicant's argument (response filed September 24, 2007, page 9) is not persuasive. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered.

(f) Claims 6 and 15 are vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 3, item (f)). The instant application does not define  $\Pi$ . Applicant's argument (response filed September 24, 2007, page 9) is not persuasive. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered.

Applicant asserts that it is known in the art that the capital letter  $\Pi$  is used to denote the mean pairwise differences per sequence and the lower-case letter  $n$  is used to refer to the mean pairwise difference per site. Applicant provided no evidence to support the assertion. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action.

- (g) The recitation of "displays a signature of positive selection" (claims 7 and 16) is vague and indefinite. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 3, item (h)). Applicant's arguments (response filed September 24, 2007, paragraph bridging page 9) are not convincing. Applicant asserts that the methods require finding a positive signal of a nucleotide region having been through an evolutionary bottleneck as being based on detection of lower nucleotide diversity in the region that has been "evolutionarily bottlenecked". How this can be done with a sample size as small as two individuals (*e.g.*, claims 1 and 3) is unexplained. Two individuals at any one nucleotide locus can show a maximum of 4 different nucleotides (one on each of the homologous chromosomes). With this result, and the instant disclosure, one of skill in the art cannot know, with clarity, whether an evolutionary bottleneck is to be inferred or not. Arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action.

Claims 1, 3, 9, 14, and 16-18 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Messier et al (U.S. Patent No. 6,274,319). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 3, second to last paragraph). Applicant's arguments (response filed September 24, 2007, pages 10-11) are not convincing. First, arguments that make reference to paragraph numbers in the specification are given no weight because the paragraphs of the specification are not numbered. Second, the assertion that the "term 'evolutionarily significant' has a defined meaning to one of skill in the art, and refers to a specific set of algorithms providing for analysis of sequence to determine a ratio between the number of nonsynonymous (sic) substitutions and synonymous

substitutions in homologous genes" is unsupported by reasoning or evidence. This is not an invitation to submit affidavit, documentary, or other evidence subsequent to a final Office action. A further assertion is made regarding the "most common type of algorithm used". The rejection stands because the definition of a polynucleotide sequence associated with a "commercially or aesthetically" relevant trait (*e.g.*, claims 1, 3, and 12) is so broad and vague and indefinite as to embrace virtually any stretch of DNA. The intended use for the claimed methods does not distinguish the claimed method steps from the methods taught in Messier et al '319.

Claims 1, 3, 9, 14, and 16 and 18 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Eyre-Walker et al (Proc. Natl. Acad. Sci. USA. 95: 4441 (1998)). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed March 22, 2007, page 3, last paragraph). Applicant's arguments (response filed September 24, 2007, pages 11-12) are not convincing. The definition of a polynucleotide sequence associated with a "commercially or aesthetically" relevant trait (*e.g.*, claims 1, 3, and 12) is so broad and vague and indefinite as to embrace virtually any stretch of DNA. Thus, the locus analyzed in Eyre-Walker et al meets the requirements of the claims. The intended use for the claimed methods does not distinguish the claimed method steps from the methods taught in Eyre-Walker et al.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

#### **OFFICIAL FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1634**

11/27/07